



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed collection; Comment Request:

#### Women's Health Initiative Observational Study

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**PROPOSED COLLECTION:** *Title:* The Women's Health Initiative (WHI) Observational Study. *Type of Information Collection Request:* Revision OMB #0925-0414. *Need and Use of Information Collection:* This study will be used by the NIH to evaluate risk factors for chronic disease among older women by developing and following a large cohort of postmenopausal women and relating subsequent disease development to baseline assessments of historical, physical, psychosocial, and physiologic characteristics. In addition, the observational study will complement the clinical trial (which has received clinical exemption) and provide additional information on the common causes of frailty, disability and death for postmenopausal women, namely, coronary heart disease, breast and colorectal cancer, and osteoporotic fractures. Continuation of follow-up for ascertainment of medical history update forms will provide essential data for outcomes assessment for this population of aging women. *Frequency of Response:* Annually. *Affected Public:* Individuals or households and health care providers. *Type of Respondents:* Study participants, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

<b>Estimate of Annual Hour Burden</b>				
Type of Respondent	Number of Respondents	Frequency of Response	Av. Time Per Response	Annual Hour Burden
OS Participants	41,495	1	20/60	13,929
Next of kin	936	1	6/60	92
Physician/Office Staff	17	1	5/60	1.4
Totals	42,448			14,023

<sup>1</sup>Annual burden is placed on health care providers and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

The annualized cost to respondents is estimated at \$308,218, assuming respondents time at the rate of \$22 per hour and healthcare provider time at the rate of \$53 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**REQUEST FOR COMMENTS:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Shari Eason Ludlam, MPH, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7913, Bethesda, MD 20892-7934, or call non-toll-free number 301- 402-2900 or E-mail your request, including your address to: Ludlams@nhlbi.nih.gov.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: January 25, 2013. \_\_\_\_\_

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Michael Lauer,  
Director, Division of Cardiovascular Sciences,  
National Heart, Lung, and Blood Institute  
National Institutes of Health

Dated: January 28, 2013. \_\_\_\_\_

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Lynn W. Susulske, Government Information Specialist  
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